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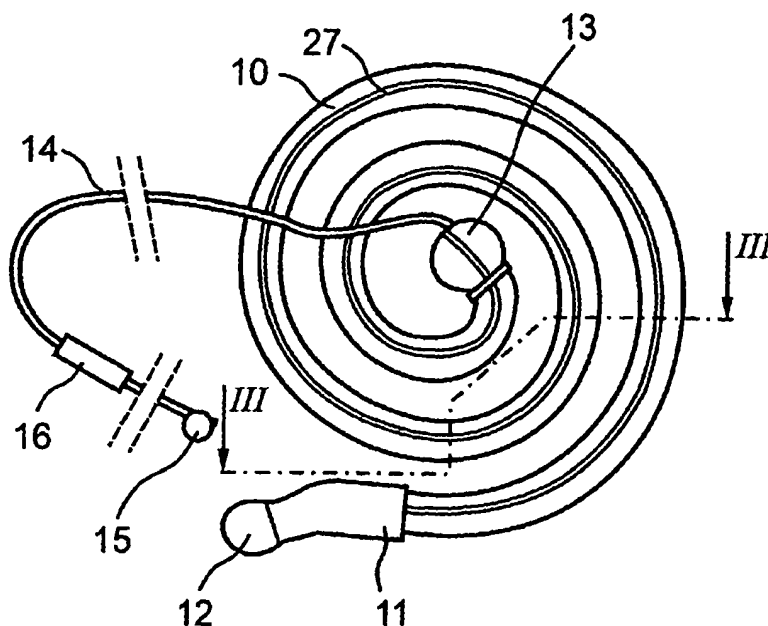
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[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR SELF-DRAINING OF URINE



(57) Abstract: A device for the drainage of the bladder through the body's own ure-thra opening outside of the human body, comprising a tube-shaped body (10). The tube-shaped body is comprised: to assume a first contracted position and for taken up within the bladder as well as a to assume a second partially extended position. At least one thread (14) extends between the bladder and an opening of the urethra and is attached at a first end of the tube-shaped body so that the tube-shaped body can be extended from the first position to the second position during the application of a pulling force upon the thread. The tube-shaped body in the second partially extended position extends in such a manner so as to exceed the distance between the bladder and the point of the urethra's closing. The tube-shaped body is comprised in

such a manner that it will return to the first position upon the release of the pulling force on the thread. The device is inserted into the bladder, in that a tube-shaped body is ex-tended and inserted into an extended tube-shaped introducing member. The introducing member is inserted in through the urethra, so that the end piece of the tube-shaped body enters the bladder. The tube-shaped body is pushed out of the tube-shaped introducing member and into the bladder during the course of which it returns to the first contracted position completely within the bladder and in the course of which the placement of a thread that is attached to the tube-shaped body and that extends outside of the urethra is left to re-main.

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METHOD AND APPARATUS FOR SELF-DRAINING OF URINE

FIELD OF THE INVENTION

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Prostate problems, such as benign prostate hyperplasia (BPH) or prostate cancer are usual occurrences among men. In many cases the symptoms experienced are very troublesome. Problems relating to the discharge of urine arise when the prostate gland swells to the extent that the urine duct, urethra, which runs through the prostate gland, is obstructed or pinched. The result of this process can lead to difficulties for the patient in being able to discharge urine at will, so-called urinary tract retention. Urinary tract retention can be either acute or chronic.

15

BACKGROUND OF THE INVENTION

The means for treating symptoms of urine retention is either surgery or another equivalent treatment, which removes the obstruction. Alternatively, the patient is required to have a catheter implanted or to learn so called self-draining. In the first case, a drainage catheter is placed into the urinary tract, from the penis and up into the bladder. The catheter is formed as a tube or a canal and is usually comprised of soft material, for example, latex, polyurethane, or silicone. At the end that lies in the bladder, the catheter is comprised of a balloon, which is blown up and prevents the catheter from slipping out. At the other end, outside of the penis, a clamp is usually attached so that the patient can open/close the catheter canal. Also urine can be collected by means of the attachment of a reservoir. The patient can also be taught to insert, on his own, a drainage catheter for him or herself into the bladder every time the urge to urinate arises and in that way can avoid the need to continually leave the catheter inside of him or herself.

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There are a number of different forms of treatment with respect to obstruction by the prostate gland, such as surgery and treatment with heat. Ag-

ing problems in the form of acute urinary tract retention can arise, however, usually during a certain time after the treatment.

As relates to disease of the prostate, the type of assistance that is available today to many of those patients who have significant problems, and who no longer can rid themselves of urine spontaneously, is chronic catheter care in the form of continual use of a catheter. Alternatively, patients can be taught the technique of inserting an emptying catheter up through the urethra into the bladder every time the urge to urinate arises. However the patient must then always carry on his or her person sterile one-time use catheters. In certain more unusual cases, a stent can be placed into the prostate in order to stretch the tissue outward and allow the passage of urine. In the greatest majority of cases, however, a catheter is used. Disadvantages with all forms of catheter treatments, whether one uses an unremovable catheter or self-insertion, are that the patient's discomfort in using a catheter as well as the limitations on quality of life issues that come with it, i.e. socially, sexually, etc. In addition, there is a relatively high risk that urinary tract infections will arise through use of a catheter.

If the patient is determined to be an unsuitable subject to undergo a radical treatment of the disease by means such as surgery, due to weakness or other reasons use of a catheter will be required for the remainder of the patient's life.

Another usual form of treatment for obstructions caused by the enlargement of the prostate gland is by means of heat treatment using microwaves, radio waves, ultra sound or laser. The object of this type of treatment is to destroy a portion of the prostate tissue nearest to the urine through the urethra in order to achieve free passage of urine in this way. With such treatments, acute retention within the urinary tract usually arises. This is a result of the fact that the heat-treated prostate tissue becomes swollen. Thus, with respect to heat treatments, it is therefore quite usual that a catheter is inserted for approximately two weeks in order to insure the drainage of urine even during this period. Despite the fact that the drainage of urine is insured by using this method, the catheter in and of itself can result in problems for the patient.

SUMMARY OF THE INVENTION

One object of the present invention is to reduce the amount of dis-
5 pleasure experienced as a result of a patient's use of a catheter in associa-
tion with the treatment of the prostate gland. Another object is to make possi-
ble the drainage of urine in association with other obstructions or another
type of illness, for example, neurogenic bladder drainage disorders in
women.

10 According to the invention there is introduced an elongated drainage
body, such as a tube, a tube-shaped body, or a similar element that is coiled
into one or more revolutions in the urine bladder in a first contracted position.
The bends in the tube make it so that it cannot spontaneously slip out
through the bladder neck. The tube is relatively soft so that it can be
15 stretched out into an extended position if additional force is applied, and so
that it will again assume its spiral shape if no outside force is applied. In the
extended position it will function as a drainage catheter.

In one embodiment an elongated slit is formed in the elongated body
to allow urine to leave the bladder and pass by the obstruction of the urethra.
20 In one end of the body, a thread is attached. A free end of the thread runs out
through the body's own urinary tract, which includes the urethra and pe-
nis/vagina. A small handle or stop can be made part of the thread in order to
inhibit the end of the thread unintentionally receding into the urethra. In a
second embodiment the elongated body is formed as a tube having a plural-
25 ity of small perforations into which the urine can run.

When the patient experiences the urge to urinate, or for any other rea-
son desires to empty the bladder, the patient pulls on the thread. The end of
the body, which is attached to the thread is drawn down through the bladder,
past the neck of the bladder and obstruction, and, in men, down through the
30 prostate gland. The thread ought only be drawn to the extent that the end
does not pass the apex of the prostate. Fittingly, a mark can be applied to the
thread so that the treating doctor or nurse can designate how far the patient

may draw so that the end will still remain inside of the prostate, yet will have passed the obstruction.

In such a manner, the patient can achieve drainage of the bladder. After drainage, the patient releases the thread, whereafter due to the spring
5 mechanism or biasing force that is a result of the tube's winding spiral shape, the end will again be drawn in so that the entire tube lies in the bladder. The biasing force can be provided also by a stiffening wire attached to or embedded in the drainage body.

With the aid of the characteristics described in the invention, the tube
10 is quite simple to apply, just as simple as inserting a normal drainage catheter.

It may be appropriate to provide the drainage body with a lubricating surface, so as to facilitate the insertion through the urethra. A preferred lubricating material is hydrogel but other materials with similar properties can be
15 used.

As a result of the invention, a number of advantages are realized, among which are the following:

1. In the case that an obstruction that is hindering spontaneous emptying is of a temporary nature, for example after heat treatment, the patient himself will notice that he is again able to empty his bladder without
20 means of assistance. He can then seek out medical assistance in order to remove the entire tube, or alternatively remove it himself.

2. The patient will experience a considerably lower degree of discomfort when he can avoid having a catheter inserted into the body or performing self-draining.
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3. The risk of infection is likely to be considerably lower compared with catheter treatment.

4. The drainage will take place from within the bladder.

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a first embodiment of a device in accordance with the invention in a receding state.

5 Fig. 2 shows a second embodiment of a device in accordance with the invention in a receding state.

Fig. 3 is a sectional view from line *III-III* of the device in Fig. 1.

Fig. 4 shows the device in Fig. 2 in an extended state and introduced into an introducing member.

10 Fig. 5 shows a driving element that can be used to push the device in Fig. 2 out of the introducing member.

Fig. 6 is a cross-sectional view of the introducing member in Fig. 4 containing an already introduced first embodiment of a driving element.

15 Fig. 7 is a cross sectional view of the introducing member in Fig. 4 containing an already introduced second embodiment of a driving element.

Fig. 8 shows a schematic view of the device in Fig. 2 fully introduced into a urine bladder.

Fig. 9 shows the device in Fig. 8 extended to a first position partially drawn down into the urethra.

20 Fig. 10 shows the device in Fig. 8 extended to a second position drawn down into the urethra into such a position that the urine can freely flow out of the urine bladder.

Fig. 11 is a schematic view drawing of an alternative embodiment of an introducing member.

25 Fig. 12 is a cross sectional view of a first alternative embodiment of the device in accordance with the invention.

Fig. 13 is a cross sectional view of a second alternative embodiment of the device in accordance with the invention in a first position.

30 Fig. 14 is a cross sectional view of the device in Fig. 13 in a second position.

Fig. 15 shows schematically injection of a lubricant into an introducing member.

Fig. 16 is a schematic side elevational view of a marker for marking the position of the drainage body.

Fig. 17 is a plan view of the marker of Fig. 16.

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DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In a first embodiment according to Fig. 1, an elongated body 10 functioning as a draining body has a first end that is attached with an end piece 11. The body 10 is formed as a flexible rod of silicon or polyurethane or a similar material and assumes, in one embodiment shown in Fig. 1, the drawn together, contracted or rolled-up form. The end piece 11 comprises a spherically formed ending 12, which makes possible the body's 10 introduction through the patient's urethra into the urine bladder. Through the application of a drawing pressure on the body 10, it can be caused to assume an extended form. A built in spring momentum, however, pulls the body 10 back to its contracted position when the pulling force is no longer applied.

In the embodiment shown in Fig. 1 the drainage body is formed with a slit 27 extending over a substantial part of the length of the drainage body. The slit 27 will allow urine to pass by the obstruction of the urethra when the drainage body 10 is in the extended position. This design of the drainage body can be manufactured in one step in a moulding process. By using silicon it is possible to produce the shape shown in Fig. 1 in one step, because it will release from the mould. Also other materials, such as polyurethane can be used. A stiffening wire (cf. Fig. 3) can be attached inside the slit 27 or be integrated with the drainage body, so as to achieve an appropriate stiffness and a property to return to the contracted position.

A second end of the body 10 is formed of a special elastic or soft section 13. The soft section 13 is connected to a first end of a thread 14. The thread 14 is sufficiently long such that it, along with the entire tube-shaped body 10 introduced into the urine bladder, stretches itself out of the urinary canal of the patient. The urinary canal of a male patient is comprised of the urethra and the penis and for a female patient, the urethra and the vagina,

more specifically, the entire distance from the urine bladder to the respective body opening.

At the thread's free end, there is a stop 15 in the form of a ball, or the like. After introduction of the body 10 into the urine bladder, the stop 15 prevents the thread from sliding into the urethra of the patient. A marker 16 on the thread makes it possible for the patient to control the drawing out of the thread 14 and body 10 to a suitable distance when used. An embodiment of the marker is shown in Fig. 16 and Fig. 17. Preferably the marker 16 is formed of a soft material. The use of the marker is described in more detail below as referenced in Figs. 8-10.

In a second embodiment according to Fig. 2, a tube-shaped and extended body 10' has a first end that is attached with an end piece 11. The body 10' is formed as a flexible tube of polyurethane or similar material and assumes, in one embodiment shown in Fig. 2, the drawn together or rolled-up form. The end piece 11 is formed of a spherically formed ending 12, which makes possible the body's 10' introduction through the patient's urethra into the urine bladder. Through the application of a drawing pressure on the body 10', it can be caused to assume an extended form. A built in spring momentum, however, pulls the body 10' back to its contracted position when the pulling force is no longer applied.

The entire tube-shaped body is provided with a plurality of holes 17 that allows for the urine to run into the body's hollow inner space. The holes 17 are accordingly evenly distributed and are of such size that the risk of occlusion is small. A larger opening 18 is provided in the end piece 11 for the drainage of the urine bladder in association with the introduction of the body therein.

Fig. 3 is a sectional view of the device 10 shown in Fig. 1. The end piece 11 and the ending 12 are formed to facilitate the insertion of the device in the urethra and the bladder. The slit 27 will allow urine to enter the tube-shaped body when the device 10 is partly or completely within the bladder. A stiffening wire 30 is attached to or embedded in the drainage body. The stiffening wire will provide the device with an appropriate stiffness that will ensure that the device regains its contracted position after being extended. It is

also possible to produce the drainage body from a material that will provide an appropriate stiffness without the stiffening wire. Other embodiments of the stiffening wire 30 are shown in Fig. 12 to Fig. 14. Preferably the stiffening wire 30 is inserted in and securely attached to the end piece 11 as shown in dashed lines.

The shape of the device can be accomplished in a one step moulding process if a suitable material such as silicone is used. Silicone will allow a negative angle on the forming tool because the adhesive forces are very low. The costs for producing the device by this method thus are very low.

Fig. 4 depicts an introducing member 19. In the embodiment shown, the introducing member 19 is comprised of a flexible tube that is open at both ends. Accordingly, the introducing member 19 is comprised of polyurethane, polyethylene or a similar material. One end of the introducing member 19 comprises a conical part 21 for the purpose of making possible the introduction of a driving element (see description of Fig. 5). The conical part can also comprise a gripping means for the doctor or nurse who is using the device. In the center of the introducing member near the conical part, a guide thread 20 is attached. The guide thread 20 runs through the introducing member and makes it possible to eject the body 10 that has been placed within the introducing member 19.

In Fig. 4, the tube-shaped body 10 is introduced into the introducing member 19 and thereby extended to assume a second position. The insertion of the tube-shaped body 10 can be facilitated by the application of a thin layer of lubricating material such as a hydrogel. When water is applied the hydrogel layer will provide a very low friction. However, in its original state outside of the introducing member 19, the body 10 will attempt to reassume the shape as described in Fig. 2. The soft section 13 of the body 10 is positioned within the introducing member 19 so that it is turned against the conical part 21 while the end piece 11 extends outside of the introducing member 19. In this way the introducing member 19 and the tube-shaped body 10 together form a device that can be inserted through the urethra. The end piece 11 and the spherically formed ending 12 have a shape that will facilitate the insertion of the device through the urethra.

Fig. 5 displays one embodiment of a driving element 22. Preferably the driving element 22 is comprised of a conical section 23 corresponding to the conical part 21 of the introducing member 19. Also in this embodiment the conical section 23 can be used as a gripping means. The driving element 22 can also be formed from polyurethane or a material with similar properties.

Fig. 6 is a cross-sectional view, which shows the introducing member 19 wherein a first embodiment of the driving element 22 has been introduced. The driving element 22 has a circular cross-section with a receding slit for receiving a guide thread 20 and the thread 14. The driving element 22 is placed into the introducing member 19 when the introducing member is in the desired position with the end piece inserted into the bladder and with the driving element 22 pressing the tube-shaped body 10 into the urine bladder.

Fig. 7 is a cross sectional view, which shows the introducing member 19 along with an alternative and preferred embodiment of a driving element 22' introduced therein. The alternative driving element 22' is tube-shaped with a central inner cavity created for the purpose of drawing through it the thread 14. The guide thread 20 is not present in the embodiment shown according to Fig. 7 and is not required.

Prior to insertion, the thread 14 is drawn through the introducing member 19 so that the thread extends outwardly into the rear conical part 21. The thread also extends through the driving element 22, 22', so as to be available from the exterior. Thereafter the user pulls on the thread 14 so that the whole body 10, with the exception of the end piece 11, is drawn into the introducing member 19. If a guide thread 20 is used, the body 10 will follow the guide thread 20 and its position will be stretched out accordingly. The end piece 11 is preferably formed with the same outer diameter as the introducing member 19. As a final aspect of the preparation for the introduction, the driving element 22, 22' is guided into the introducing member 19 from its end possessing the conical part 21 until the driving element 22, 22' lies against the soft section 13 of the body 10. The introduction of the driving element 22, 22' can also be postponed to a later time.

In the above-described embodiment, the entire device is inserted in its full length through the urethra and up into the bladder. The introducing member 19 should also be of such length so that the end piece is ensured of being introduced into the urine bladder. In a simple manner, the end piece's position can be monitored by the fact that urine drains from the introducing member 19. The driving element 22 can therewith be drawn out of the introducing member 19, or be provided with channels running along its surface for the purpose of drawing away urine when the driving element 22 is inserted into the introducing member 19.

After ensuring that the end piece is correctly positioned, the full-length of the driving element 22, 22' is inserted into the introducing member 19, wherewith the body 10 passes into the bladder and assumes its contracted form. Thereafter the driving element 22, 22' along with the introducing member 19 are drawn completely out of the urethra. During removal of the driving element 22, 22' and the introducing member 19, the thread 14 should not be placed under any pressure, but should slide out freely through and from the introducing member 19 and the driving element 22'.

Fig. 8 is a schematical view of the body 10' as introduced into the bladder 24 and with its end piece 11 resting against the urine bladder's wall. The thread 14 runs down through the point of the urethra's closing 25 and is accessible outside of the body. The point of the urethra's closing 25 is, as in the drawing provided, caused by the prostate tissue 26 that has been enlarged.

When the urge to urinate arises or during other drainage of the bladder, the patient draws the thread 14, whereafter conditions in accordance with Fig. 9 will arise. The soft section 13 has been drawn down through the neck of the bladder and presses down upon tissue that is blocking the urethra when force is applied to the thread 14.

Additional drawing on the thread 14 results in the body 10' being drawn down through the prostate 26 and creates a canal, through which the patient can empty his bladder. These circumstances are exhibited in Fig. 10, where the soft section 13 has been completely drawn past the point of the urethra's closing 25. Urine can then freely pass through the tube-shaped

body 10'. After drainage has occurred the thread 14 is released wherewith the body 10' slowly returns to the contracted position shown in Fig. 1, Fig. 2 and Fig. 8.

5 If the condition which has caused the point of the urethra's closing 25 abates, for example after a certain time subsequent to heat treatment of the prostate, the entire device can be removed by the patient simply drawing out the entire thread 14. The body 10' will then follow in the same path of removal without damaging the urethra or other tissue.

10 In addition to polyurethane other similar pliable materials can be used to form the tube-shaped body 10', the introducing member 19, and the driving element 22, 22'. An example of such material is silicone. The introducing member 19, however, should have a certain rigidity so that the tube-shaped body can be safely pushed through it.

15 In the embodiment according to Fig. 11, the introducing member is comprised so that a flexible guide thread 29 has an outer dimension less than the diameter of the tube-shaped body's 10 inner diameter. In order to facilitate the use of the introducing member, the thread 29 is provided with a gripping means 28. In the exhibited embodiment, a circular cross-section is used. The driving element 22' also in this embodiment is tube-shaped.

20 In the embodiment shown in Fig. 11 the driving element 22', like the entirety of the tube-shaped body 10, is guided via the flexible guide thread 29. Accordingly, the flexible guide thread 29 is extended throughout essentially the entirety of the tube-shaped body 10. One advantage of this embodiment is that the tube-shaped body 10 can be created to possess a greater outer diameter and therewith offer enhanced drainage capacities.
25 The flexible guide thread 29 can be comprised of a spun or wound piano wire or a similar material and should be sufficiently rigid so that the tube-shaped body 10 remains in the second extended position when it is moved over the guide thread 29.

30 Fig. 12 shows a first embodiment of the drainage body 10. A slit 27 is formed along the body to allow urine to enter a longitudinally extending cavity within the body and to escape there through. The spherically formed ending 12 is partly shown. In the embodiment shown in Fig. 12 the stiffening wire 30

is embedded in the body 10. The stiffening wire 30 preferably should not be in a direct contact with urine.

In the alternative embodiment shown in Fig. 13 and Fig. 14 the stiffening wire 30 extends in a recess in the bottom of a longitudinally extending cavity within the body. A tongue 31 having a spherically formed tip 32 extends from an inner surface of the body 10. After insertion of the stiffening wire 30 into the recess the tongue 31 is bent over the wire 30 and pressed down into a recess 33. The recess is formed to receive and to retain the tip 32 of the tongue as shown in Fig. 14.

Fig. 15 shows a section of the introducing member 19 and the elongated body 10 with the soft spherical end 13 inserted therein. The driving element 22' is also inserted in the introducing member 19, a small space being left between the elongated body 10 and the. When the driving element 22' is advanced through the introducing member 19 it may be appropriate to facilitate the movement. An aperture 34 is formed in the introducing member 19 to allow the introduction of a lubricant 35 to the interior of the introducing member 19.

In the embodiment shown in Fig. 16 and Fig. 17 a first bowl shaped element 36 and a second bowl shaped element 37 connected by a hinge section 38 form the marker 16. A snap lock mechanism is formed by indentations 39 in the first bowl shaped element 36 and protruding elements 40 on the second bowl shaped element 37. A first cylindrical member 41 on the first bowl shaped element 36 is used to wind the thread 14 up, and a second cylindrical member 42 on the second bowl shaped element 37 will lock the thread in position when the two bowl shaped elements are pressed together.

CLAIMS

1. A device for the drainage of the urine bladder having a point of a closing or an obstruction of the urethra, the draining occurring through the body's own urethra opening outside of the human body, comprising an elongated drainage body (10) having a drainage channel extending in the longitudinal direction of the drainage body (10), wherein
- the drainage body is formed so as to assume a first contracted position and being taken up within the bladder,
- the drainage body is formed so as to assume a second partially extended position,
- a thread (14) having a length sufficient to extend between at least the bladder and an opening of the urethra and being connected with a first end of the drainage body for the purpose of extending the drainage body from the first position to the second position upon the exertion of a pulling force upon the thread,
- the drainage channel of the drainage body in the second partially extended position has a length which exceeds the distance between the bladder and the point of a closing or the obstruction of the urethra and
- the drainage body is formed in such a manner that it returns to the first position upon the release of the pulling force on the thread.
2. A device in accordance with claim 1, wherein the drainage body (10) is formed in a spiral shape in the first contracted position.
3. A device in accordance with claim 1, wherein the drainage body (10) is folded in the first contracted position.
4. A device in accordance with claim 1, wherein the drainage body is formed of polyurethane or silicon or a similar flexible material.

5. A device in accordance with claim 1, wherein the drainage body is formed with a slit having a length in the longitudinal direction of the drainage body exceeding the distance between the bladder and the point of a closing or the obstruction of the urethra.
- 5
6. A device in accordance with claim 1, wherein the drainage body is formed with a tubular shape with an inner cavity having a length in the longitudinal direction of the drainage body exceeding the distance between the bladder and the point of a closing or the obstruction of the urethra and
- 10 wherein drainage body is formed with a plurality of openings into said inner cavity.
7. A device in accordance with claim 1, wherein an end piece (11) having a rounded, ending form is attached to a second end of the drainage body
- 15 (10).
8. A device in accordance with claim 7, wherein the end piece (11) is formed with a through opening (18) connected to an inner space of the drainage body (10).
- 20
9. A device in accordance with claim 1, wherein the first end of the drainage body (10) ends with a soft section (13).
10. A device in accordance with claim 1, wherein the drainage body (10) is
- 25 formed with an inner cavity and a plurality of perforations (17) that allows the penetration of urine into and out of the inner cavity of the drainage body (10).
11. A device in accordance with claim 1, wherein a stiffening wire (30) is provided in the drainage body (10) to bias said body into said first contracted
- 30 position.
12. A device in accordance with claim 11, wherein the stiffening wire (30) is embedded in the drainage body (10).

13. A device in accordance with claim 11, wherein the drainage channel of the drainage body (10) is provided with a flexible tongue (31) having a spherically formed tip (32) and the flexible tongue (31) being bendable to a position where the spherically formed tip (32) is received in a longitudinally extending recess in a wall of the drainage channel to enclose the stiffening wire (30).

14. An introducing member (19) for the insertion into the bladder of a device in accordance with claim 1, wherein
an extended cavity runs through the entire introducing member (19),
the cavity's dimensions correspond to the external dimensions of the body (10), so that the body (10) can be received therein when in an extended position.

15. An introducing member (19) in accordance with claim 14 forming together with the drainage body (10) a unit that is insertable in the urethra, wherein an end piece (11) having a rounded, ending form is attached to a second end of the drainage body (10) and extends out of the introducing member (19) to facilitate the insertion in the urethra.

16. An introducing member (19) for the insertion into the bladder of a body (10) in accordance with claim 1, wherein
the introducing member (19) comprises a flexible guide thread having an external dimension that is less than that of the body's (10) inner dimension, so that the introducing member (19) can be received within the body (10)
the flexible guide thread is formed with sufficient rigidity so that the body (10) assumes an extended position when the introducing member (19) is inserted therein.

17. A method for inserting a drainage body into the bladder, the drainage body, wherein

the drainage body is formed so as to assume a first contracted position and being taken up within the bladder,

5 the drainage body is formed so as to assume a second partially extended position,

a thread (14) having a length sufficient to extend between at least the bladder and an opening of the urethra and being connected with a first end of the drainage body for the purpose of extending the drainage body from the first position to the second position upon the exertion of a pulling force upon the thread,

10 the drainage channel of the drainage body in the second partially extended position has a length which exceeds the distance between the bladder and the point of a closing or the obstruction of the urethra and

15 the drainage body is formed in such a manner that it returns to the first position upon the release of the pulling force on the thread,

including the steps of

20 inserting the drainage body into a hollow introducing member, leaving an end piece of the drainage body having a rounded, ending form extending from the introducing member,

inserting the introducing member into the urethra to a position where the end piece is received in the bladder, and

25 pushing the drainage body into the bladder.

18. A method for drainage of the bladder through the body's own urethra opening outside of the human body, where a closing or a obstruction is present in the urethra and preventing normal passage of urine from the bladder, including the steps

30

inserting a drainage body into the bladder while maintaining a section of a thread that is attached to the drainage body extending outside the urethra,

5 extending said drainage body from a first contracted position to a second extended position against a biasing force by exerting a pulling force to said extending section of the thread for introducing at least a first part of the drainage body to a position located distally from the point of the urethra's closing or the obstruction while maintaining a second part of the drainage body in a contracted position within the
10 bladder,

allowing urine to run through at least one opening in the drainage body from the bladder through the drainage body past the urethra's closing or the obstruction to a position outside the urethra and

15 ending the exertion of the pulling force so as to allow the biasing force to bring the drainage body back to said first contracted position.

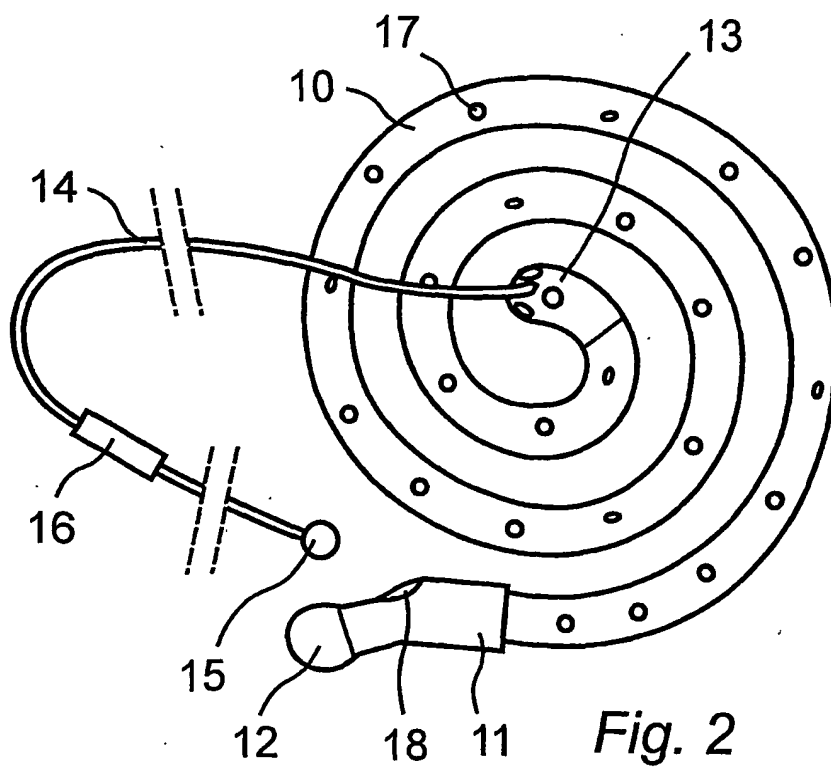
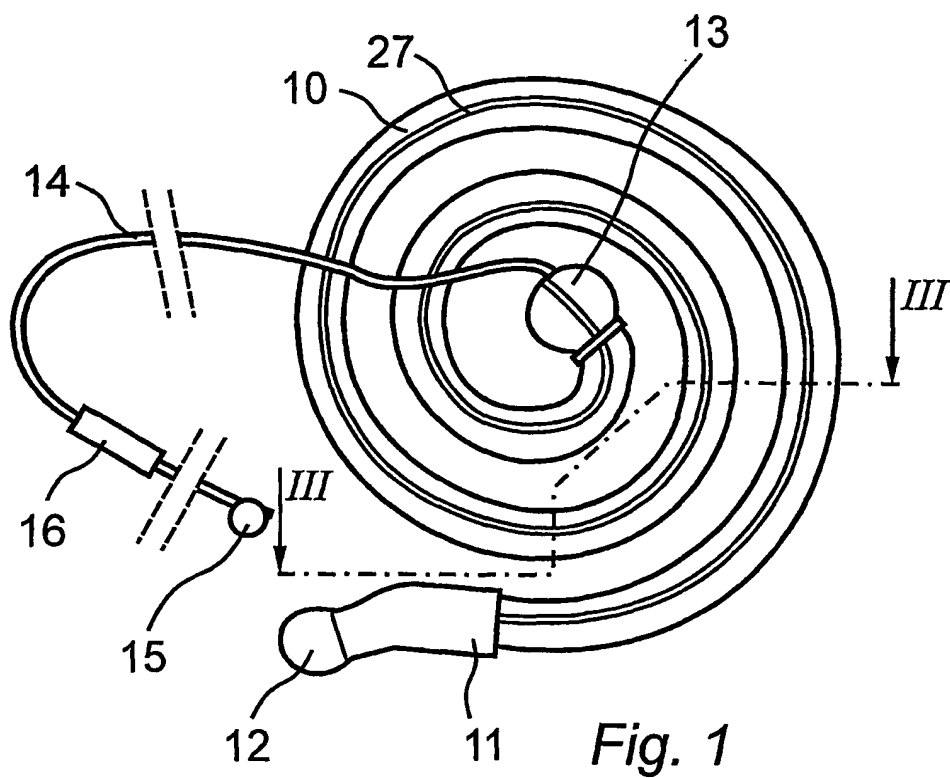
19. A method for the insertion of a device for the drainage of the bladder through the body's own urethra opening outside of the human body, wherein

20 a body extends from a first contracted position to an extended second position and is inserted into an elongated tube-shaped introducing member,

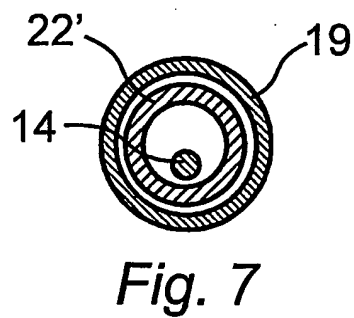
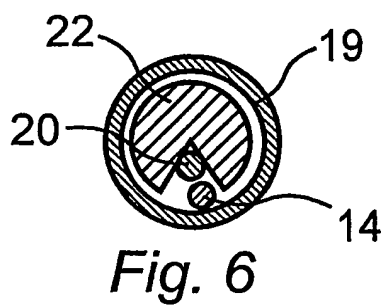
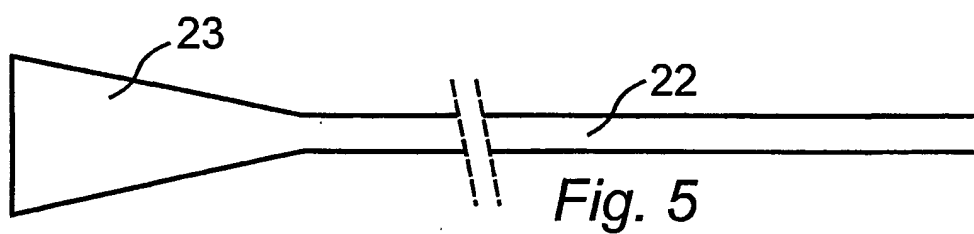
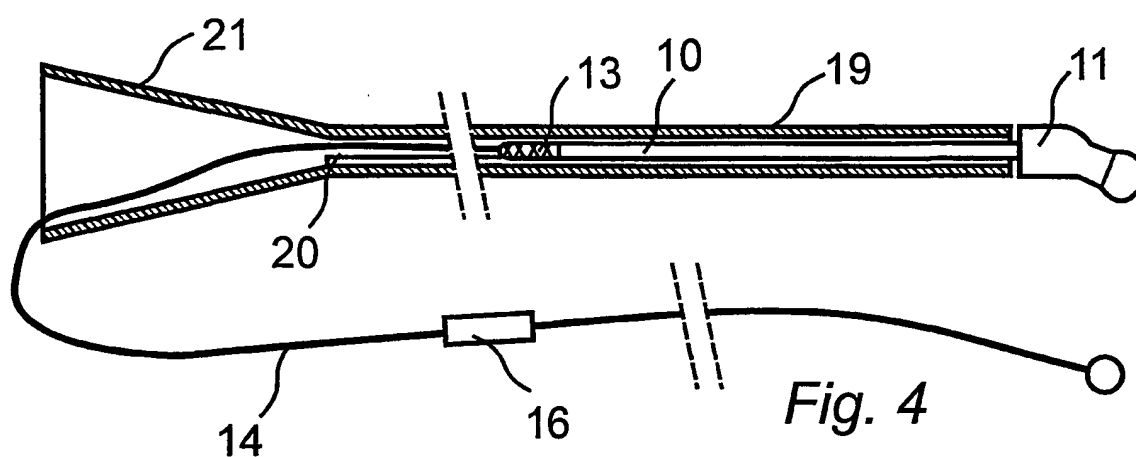
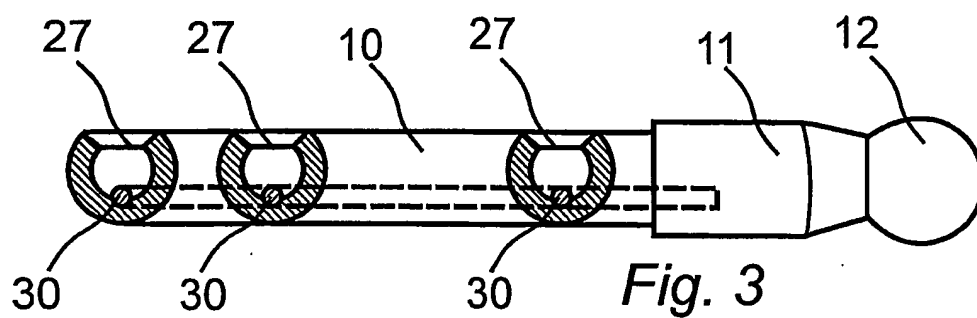
25 the tube-shaped introducing member is inserted through the urethra, so that an end piece of the tube-shaped body passes into the bladder,

30 the body is pushed out of the tube-shaped introducing member and into the bladder during the course of which the return of the body to the first contracted position occurs completely within the bladder and in the course of which the placement of a thread extends outside of the urethra that is attached to the tube-shaped body.

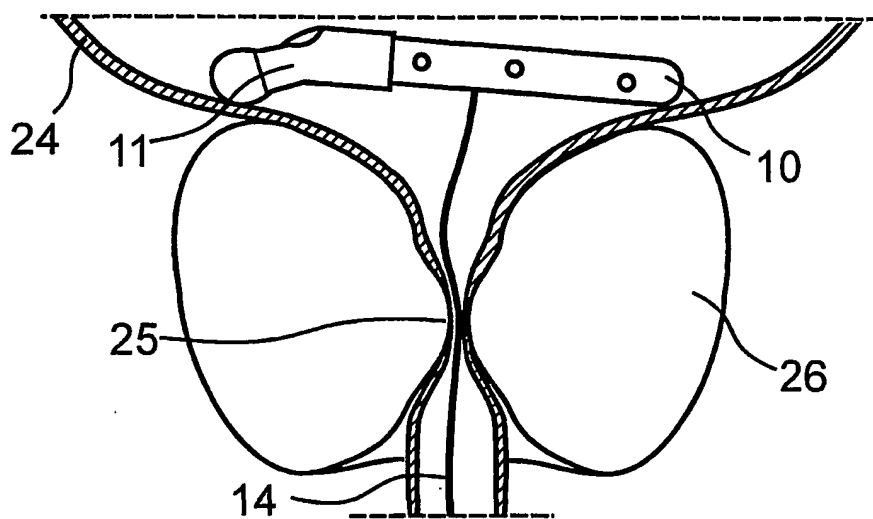
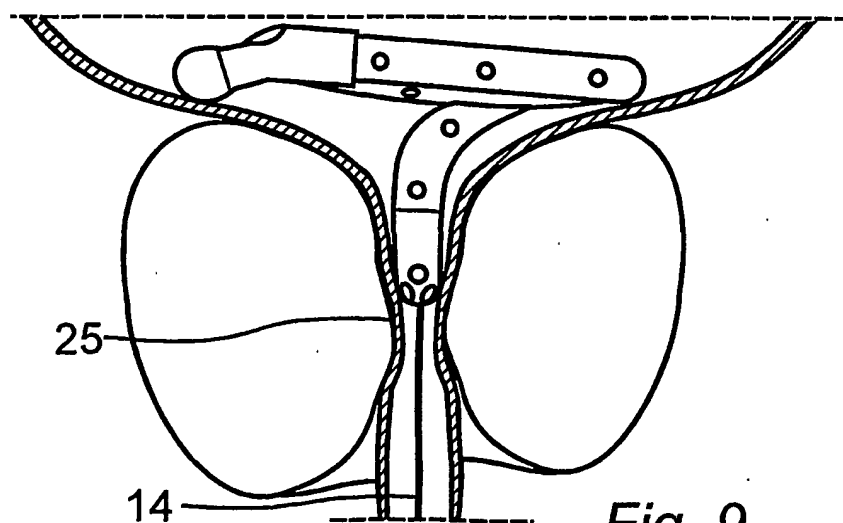
1/5

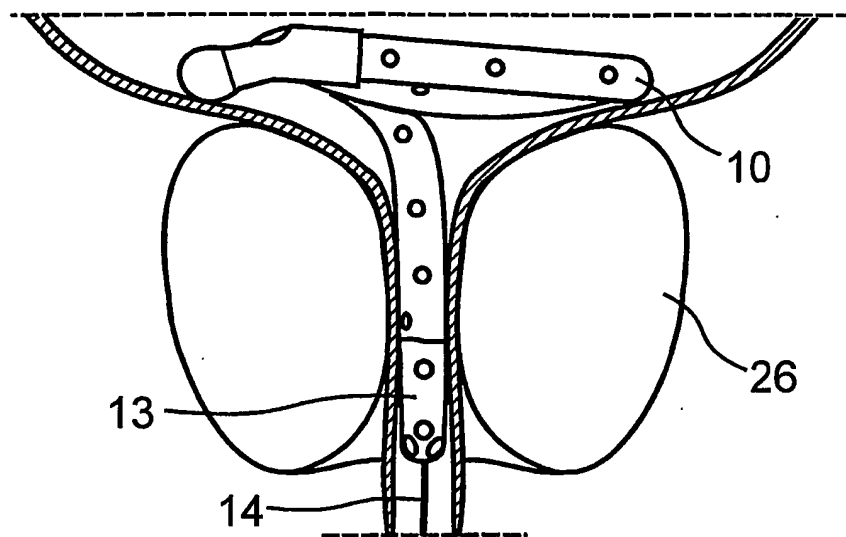
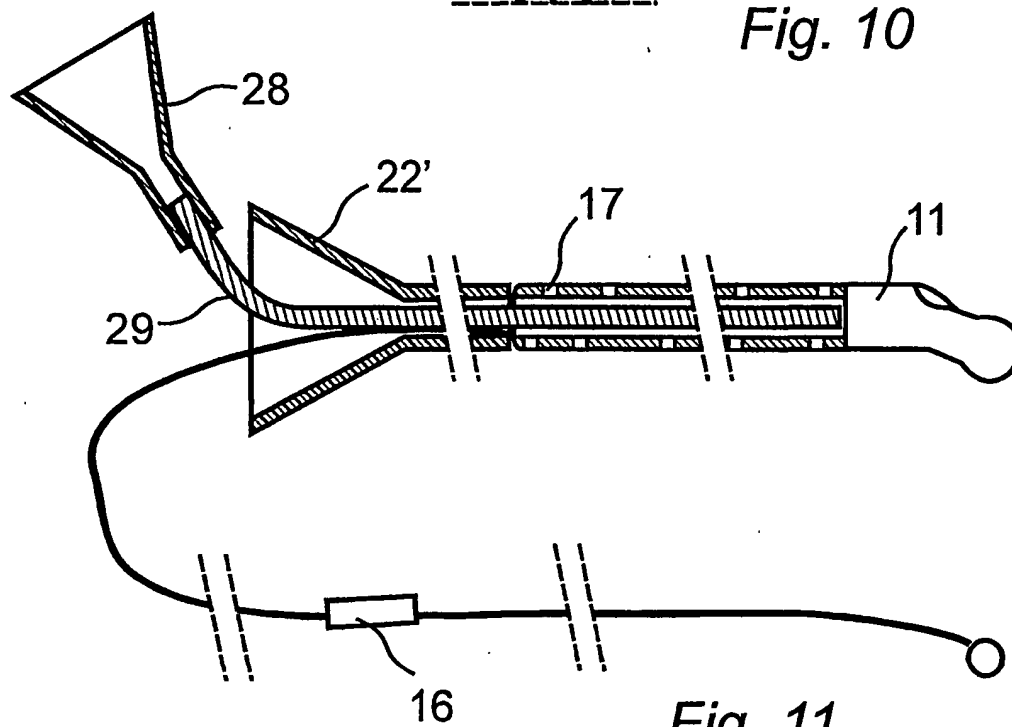


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*Fig. 8**Fig. 9*

*Fig. 10**Fig. 11*

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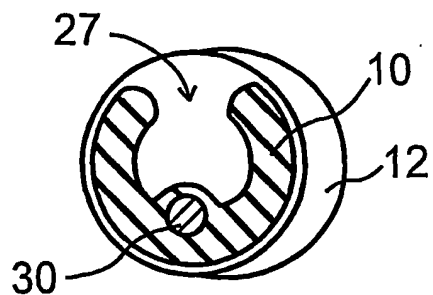


Fig. 12

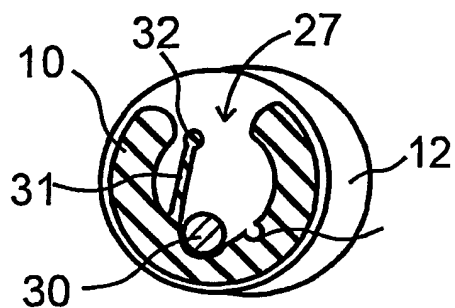


Fig. 13

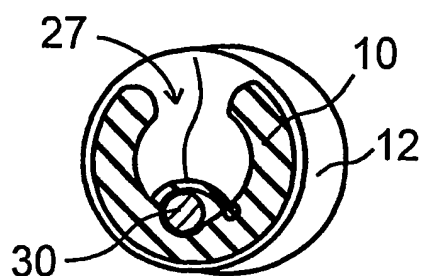


Fig. 14

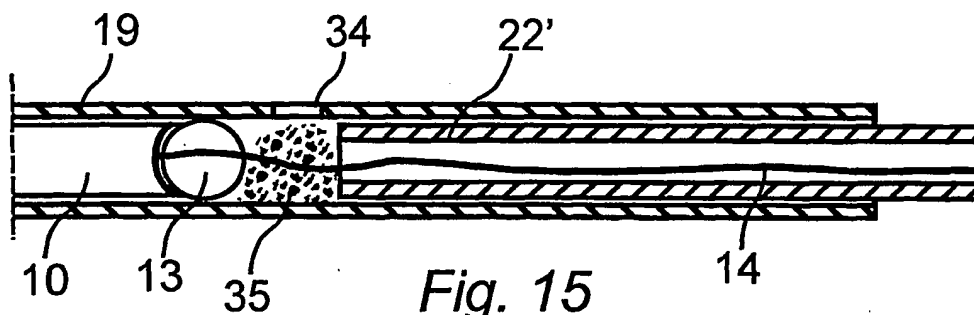


Fig. 15

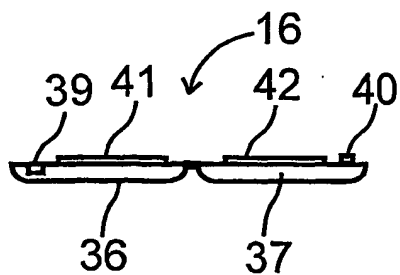


Fig. 16

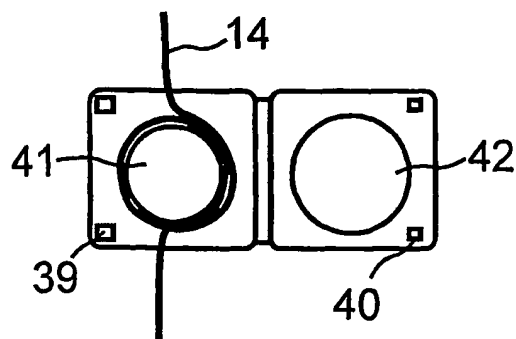


Fig. 17

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 01/02219

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 25/00 // A61F 5/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0733379 A1 (CONTIMED INC), 25 Sept 1996 (25.09.96), figures 1-15, claims 1-51 --	1-16
A	DE 3517813 A1 (WIEDECK, J-G), 20 November 1986 (20.11.86), figures 1-3, claims 1-5 -- -----	1-16

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

26 February 2002

Date of mailing of the international search report

07-03-2002

Name and mailing address of the ISA/
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Agneta Ånggård/EK
 Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE01/02219

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-19
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 17-19 relate to a therapeutic method practised on the human body. Thus, the International Search Authority is not required to carry out an international search for these claims (Rule 39.1(iv)).
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/01/02

International application No.

PCT/SE 01/02219

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
EP	0733379	A1	25/09/96	JP	3177445 B	18/06/01
				JP	9010298 A	14/01/97
				TW	422710 B	00/00/00
				US	5562622 A	08/10/96
				US	5738654 A	14/04/98
				CA	2191814 A	27/06/97

DE	3517813	A1	20/11/86	NONE		

INTERNATIONAL SEARCH REPORT

International Application No
PCT/DE 03/00922

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
✓ X	US 5 887 593 A (LEVIUS DEZSO K) 30 March 1999 (1999-03-30) column 3, line 53 - column 7, line 4; figures	1-5, 7, 8, 13, 15
✓ X	WO 02/36192 A (BOLMSJOE MAGNUS ; PROSTALUND OPERATIONS AB (SE)) 10 May 2002 (2002-05-10) page 6, column 8 - page 11, column 29; figures 1, 4, 8-11	1-5, 8, 13, 15
✓ A	US 3 630 206 A (GINGOLD BRUCE) 28 December 1971 (1971-12-28) column 2, line 26 - column 3, line 50; figures 1-5	1

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Date of the actual completion of the international search

29 March 2004

Date of mailing of the international search report

07/04/2004

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/DR 03/00922

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			GB 2326349 A	23-12-1998
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